

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI**

THOMAS LELAND,)	
)	
Plaintiff)	
)	
v.)	
)	Case No. 6:16-cv-03023-MDH
BRISTOL-MYERS SQUIBB COMPANY,)	
OTSUKA PHARMACEUTICAL CO., LTD.,)	
AND OTSUKA AMERICA)	
PHARMACEUTICAL INC.,)	
)	
Defendants)	

**DEFENDANT OTSUKA AMERICA PHARMACEUTICAL, INC.’S
ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Otsuka America Pharmaceutical Inc. (“OAPI”) answers the Complaint and Jury Demand of Plaintiff Thomas Leland as follows: OAPI denies each allegation in the Complaint except those expressly admitted below. OAPI also states that, to the extent allegations in the Complaint refer generally to “Defendants,” “Otsuka,” “Otsuka entities,” and/or the “Otsuka Group,” OAPI answers the allegations only as to OAPI. To the extent that allegations in the Complaint refer to defendants other than OAPI, OAPI refers the Court to the other defendants’ responses to the Complaint, and states that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations.

INTRODUCTION

1. To the extent this paragraph is intended to summarize allegations set forth in Plaintiff’s Complaint, the allegations are improper and require no response. To the extent the allegations contained in this paragraph assert legal conclusions, no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

2. OAPI states that it distributes and markets Abilify® in the United States and that the FDA-approved label for Abilify® sets forth the approved indications for and forms of Abilify®. OAPI denies the remaining allegations of this paragraph.

3. OAPI denies the allegations contained in this paragraph.

4. OAPI denies the allegations contained in this paragraph.

5. Answering the allegations of this paragraph, OAPI states that information about the known risks associated with Abilify® use are contained in the FDA-approved label for Abilify®, that labeling in other jurisdictions speak for themselves, and OAPI denies any characterization of, or commentary about, the referenced documents. OAPI denies the remaining allegations contained in this paragraph.

6. OAPI denies the allegations contained in this paragraph.

PARTIES

7. OAPI states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph and therefore denies the same.

8. To the extent the allegations contained in this paragraph assert legal conclusions, no response is required. As to the remaining allegations of this paragraph, OAPI denies the allegations contained in the last sentence of this paragraph and OAPI states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies the same.

9. OAPI denies the allegations contained in this paragraph.

10. OAPI denies the allegations contained in this paragraph.

11. OAPI states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph and therefore denies the same.

12. OAPI states that its parent company is Otsuka America, Inc. (“OAI”) and that OAI is owned by Otsuka Pharmaceutical Co., Ltd. (“OPC”), which is, on information and belief, a Japanese corporation based in Japan, and that OPC owns the trademark for Abilify®. OAPI further states, on information and belief, that OAI is also the parent company of Otsuka Pharmaceutical Development & Commercialization, Inc. (“OPDC”), and Otsuka Maryland Medicinal Laboratories, Inc. (“OMML”). OAPI states that it lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and therefore denies the same.

13. To the extent that the allegations contained in this paragraph assert a legal conclusion, no response is required. To the extent a response is required, OAPI states that it is incorporated in Delaware and that OAPI has offices at 508 Carnegie Center Princeton, New Jersey. OAPI states further that it has distributed and marketed Abilify® in the United States, that it is responsible for all pharmaceutical commercial activities in the United States with respect to Abilify, and that it collaborated with Bristol-Myers Squibb Company in the commercialization of Abilify® in the United States. OAPI denies the remaining allegations contained in this paragraph.

14. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

15. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI states that it collaborated with Bristol-Myers Squibb Company in the commercialization of Abilify® in the United States, and otherwise denies the remaining allegations contained in this paragraph.

16. To the extent the allegations contained in this paragraph assert legal conclusions, no response is required. OAPI states that it has distributed and marketed Abilify® in the United States and that it collaborated with Bristol-Myers Squibb Company in the commercialization of Abilify® in the United States. OAPI denies the remaining allegations contained in this paragraph.

17. OAPI states that it has distributed and marketed Abilify® in the United States and that it collaborated with Bristol-Myers Squibb Company in the commercialization of Abilify® in the United States. OAPI denies the remaining allegations contained in this paragraph.

JURISDICTION

18. The allegations contained in this paragraph assert legal conclusions to which no response is required.

19. The allegations contained in this paragraph assert legal conclusions to which no response is required.

20. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

21. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

22. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI states that it does not contest personal jurisdiction in this case, but reserves its right to contest personal jurisdiction in other cases.

FACTUAL BACKGROUND

23. OAPI admits the allegations contained in this paragraph.

24. To the extent that allegations in this paragraph refer to Defendants other than OAPI, OAPI states that it lacks knowledge sufficient to form a belief as to the truth of the allegations and therefore denies the same. OAPI denies the remaining allegations contained in this paragraph.

25. Answering the allegations in this paragraph, OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

26. Answering the allegations in this paragraph, OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

27. Answering the allegations in this paragraph, OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

28. Answering the allegations in this paragraph, OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

29. OAPI denies the allegations contained in this paragraph.

30. OAPI denies the allegations contained in this paragraph.

31. OAPI denies the allegations contained in this paragraph.

32. OAPI states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph and therefore denies the same.

33. Answering the allegations of this paragraph, OAPI states that the FDA has determined that Abilify® is safe and effective for use in accordance with its FDA-approved label, and the label speaks for itself. OAPI denies the remaining allegations in this paragraph.

34. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

35. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

36. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

37. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

38. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

39. Answering the allegations in this paragraph, OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

40. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

41. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

42. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

43. Answering the allegations in this paragraph, OAPI states that the cited documents speaks for themselves and denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

44. OAPI denies the allegations contained in this paragraph.

45. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

46. Answering the allegations in this paragraph, OAPI states that the allegations contained in this paragraph recite the contents of documents, which speak for themselves and

denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

47. OAPI states that the clinical pharmacology of Abilify® is set forth in the FDA-approved label for Abilify®. Except as stated in the FDA-approved label for Abilify®, OAPI denies the allegations of this paragraph.

48. OAPI states that the allegations are based on documents in the “scientific literature,” the referenced documents speak for themselves and OAPI denies any characterization of, or commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

49. Answering the allegations in this paragraph, OAPI states that the clinical pharmacology of Abilify® is set forth in the FDA-approved label for Abilify®. Responding further, OAPI states that the allegations of this paragraph appear to refer to documents in the “scientific literature,” the referenced documents speak for themselves and denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

50. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

51. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

52. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

53. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

54. Answering the allegations in this paragraph, OAPI states that the cited documents speak for themselves and denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

55. OAPI states that the referenced documents speak for themselves and denies any characterization of, or commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

56. The allegations contained in this paragraph refer to certain “case reports.” OAPI states that the referenced documents speak for themselves and denies any characterization of, or commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

57. The allegations contained in this paragraph refer to certain “case reports.” OAPI states that the referenced documents speak for themselves and denies any characterization of, or commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

58. The allegations contained in this paragraph refer to certain “case reports.” OAPI states that the referenced documents speak for themselves and denies any characterization of, or

commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

59. The allegations contained in this paragraph refer to certain “case reports.” OAPI states that the referenced documents speak for themselves and denies any characterization of, or commentary about, the referenced documents. Except as stated, OAPI denies the remaining allegations of this paragraph.

60. Answering the allegations in this paragraph, OAPI states that the cited documents speak for themselves and denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

61. The allegations in this paragraph assert legal conclusions to which no response is required. To the extent a response is deemed necessary, OAPI states that the cited regulation speaks for itself and denies any attempt to characterize the cited regulation. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

62. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

63. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

64. Answering the allegations in this paragraph, OAPI states that the cited documents speak for themselves and denies any characterization of, or commentary about, the cited documents. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

65. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

66. OAPI denies the allegations contained in this paragraph.

67. OAPI denies the allegations contained in this paragraph.

68. OAPI denies the allegation in the first sentence of this paragraph. Answering the remaining allegations contained in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

69. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

70. OAPI denies the allegations in the first sentence of this paragraph. OAPI states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence and therefore denies the same. The allegations of the third sentence appear to refer to a certain “report[]”; OAPI states that the referenced document speaks for itself and denies any characterization of, or commentary about, the referenced document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

71. Answering the allegations in this paragraph, OAPI states that the cited document speaks for itself and denies any characterization of, or commentary about, the cited document. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

72. OAPI denies the allegations contained in this paragraph.

73. OAPI states that it has marketed Abilify® in the United States. OAPI further states that any advertisements for Abilify® speak for themselves and denies any attempt to characterize the advertisements. OAPI denies the remaining allegations contained in this paragraph.

74. OAPI denies the allegations contained in this paragraph.

75. OAPI denies the allegations contained in this paragraph.

76. OAPI denies the remaining allegations contained in this paragraph.

77. OAPI denies the allegations contained in this paragraph.

78. OAPI states that the FDA-approved label for Abilify® sets forth its risk information and speaks for itself. OAPI denies the remaining allegations of this paragraph.

79. Answering the allegations in this paragraph, OAPI states that the FDA-approved label for Abilify® speaks for itself and denies any characterization of, or commentary about, the FDA-approved label for Abilify®. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

80. Answering the allegations in this paragraph, OAPI states that the FDA-approved label for Abilify® speaks for itself and denies any characterization of, or commentary about, the FDA-approved label for Abilify®. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

81. Answering the allegations in this paragraph, OAPI states that the FDA-approved label for Abilify® speaks for itself and denies any characterization of, or commentary about, the FDA-approved label for Abilify®. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

82. Answering the allegations in this paragraph, OAPI states that the cited website speaks for itself and denies any characterization of, or commentary about, the cited website. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

83. Answering the allegations in this paragraph, OAPI states that the cited website speaks for itself and denies any characterization of, or commentary about, the cited website. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

84. OAPI states that it lacks knowledge sufficient to form a belief as to the truth of the allegations and therefore denies the same.

85. OAPI states that it lacks knowledge sufficient to form a belief as to the truth of the allegations and therefore denies the same. Except as stated, OAPI denies the remaining allegations contained in this paragraph.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

86. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

87. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

88. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

89. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

90. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

91. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

FIRST CAUSE OF ACTION
Strict Liability – Design, Manufacturing and Warning

92. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

93. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

94. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

95. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

96. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

97. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

98. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

99. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

100. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

101. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

102. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

SECOND CAUSE OF ACTION
Breach of Express Warranty by Defendants

103. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

104. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

105. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

106. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

107. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

108. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

109. OAPI states that the FDA has determined that Abilify® is safe and effective for use in accordance with its FDA-approved label, and the label speaks for itself. Answering further, the allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

110. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

111. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

112. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

113. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

114. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

FOURTH CAUSE OF ACTION **Negligence**

115. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

116. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

117. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

118. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

119. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

120. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph and all subparts thereof.

121. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

FIFTH CAUSE OF ACTION
Negligence Per Se

122. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

123. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

124. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph and all subparts thereof.

125. Answering the allegations contained in this paragraph, OAPI states that the statutes and regulations speak for themselves, and any attempt to characterize them is denied. The allegations contained in this paragraph further assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

126. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

127. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

SIXTH CAUSE OF ACTION Negligent Misrepresentation

128. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

129. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

130. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

131. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

132. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

133. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

134. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

135. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

136. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

SEVENTH CAUSE OF ACTION
Violation of Missouri Merchandising Practices Act

137. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

138. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

139. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

140. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

EIGHTH CAUSE OF ACTION Fraudulent Concealment

141. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

142. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

143. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

144. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph and all subparts thereof.

145. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI states that it is without

knowledge or information sufficient to form a belief about the truth of any allegations concerning the “olmesartan products” and therefore denies same; OAPI denies the remaining allegations contained in this paragraph.

146. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

147. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

148. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

149. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

150. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

NINTH CAUSE OF ACTION Punitive Damages

151. Answering the allegations of this paragraph, OAPI repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

152. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

153. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

154. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

155. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

156. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

157. The allegations contained in this paragraph assert legal conclusions to which no response is required; to the extent any response is required, OAPI denies the allegations contained in this paragraph.

158. OAPI denies each and every allegation contained in Plaintiff's Complaint not specifically admitted or otherwise responded to here.

PRAYER FOR RELIEF

Answering the “WHEREFORE” paragraph under the heading “Prayer for Relief,” including all subparts thereof, OAPI denies that Plaintiff is entitled to any relief against OAPI whatsoever.

DEMAND FOR JURY TRIAL

OAPI demands a jury trial on all issues so triable.

AFFIRMATIVE DEFENSES

As for additional defenses to the Complaint, and without assuming any burden of pleading or proof that would otherwise rest on Plaintiff, Otsuka America Pharmaceutical Inc. alleges as follows:

First Affirmative Defense

The Complaint fails to state, in whole or in part, a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the applicable statute of limitations and/or repose.

Third Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the equitable defenses of laches, waiver, and/or estoppel.

Fourth Affirmative Defense

OAPI affirmatively pleads the doctrines contained in § 402A of the *Restatement (Second) of Torts*, comment k to § 402A of the *Restatement (Second) of Torts*, and the *Restatement (Third) of Torts: Products Liability*.

Fifth Affirmative Defense

Plaintiff's claims are barred because the injuries allegedly sustained by Plaintiff were not proximately caused by any act or omission of OAPI.

Sixth Affirmative Defense

Plaintiff knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Complaint. Under the doctrines of assumption of the risk and/or informed consent, this conduct bars, in whole or in part, the damages that Plaintiff seeks to recover.

Seventh Affirmative Defense

Plaintiff's claims are barred because the injuries allegedly sustained by Plaintiff were actually or proximately caused, in whole or in part, by independent, unforeseeable, superseding, and/or intervening cause.

Eighth Affirmative Defense

Plaintiff's alleged injuries and damages, if any, were caused in whole or in part by the acts and omissions of third parties over whom OAPI had no authority or control, including without limitation, misuse of any products by such third parties.

Ninth Affirmative Defense

Plaintiff's recovery, if any, should be reduced pursuant to the comparative and/or contributory negligence, fault, responsibility, or causation of others, including, but not limited to, Plaintiff.

Tenth Affirmative Defense

If Plaintiff was injured by any product manufactured, sold, marketed, or distributed by OAPI, those injuries occurred because the product was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and in

disregard of instructions and directions regarding its use. Such misuse was not reasonably foreseeable to OAPI.

Eleventh Affirmative Defense

Plaintiff's claims are barred because any injuries and damages allegedly sustained by Plaintiff were the result of pre-existing or subsequent conditions that are unrelated to the use of any product manufactured, sold, marketed, or distributed by OAPI.

Twelfth Affirmative Defense

Plaintiff's claims are barred because any injuries and damages allegedly sustained by Plaintiff as a result of any product manufactured, sold, marketed, or distributed by OAPI were caused by an idiosyncratic reaction to the product that was not reasonably foreseeable to OAPI.

Thirteenth Affirmative Defense

Plaintiff's claims are barred because of Plaintiff's failure to mitigate the alleged damages.

Fourteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, release, discharge, and accord and satisfaction. Plaintiff's claims are also barred by the doctrine of res judicata, including the rule against the splitting of claims.

Fifteenth Affirmative Defense

OAPI denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of OAPI, or at the instruction or subject to the control of OAPI with regard to any of the actions described in the Complaint; thus, OAPI is not liable for any acts or omissions of such third parties as a matter of law.

Sixteenth Affirmative Defense

OAPI declares that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

Seventeenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Defendant acted in good faith at all times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

Eighteenth Affirmative Defense

OAPI provided adequate and complete warnings concerning its products to Plaintiff's prescribing physicians. Therefore, any claims by Plaintiff for inadequate warnings are controlled by, and barred under, the learned intermediary, informed intermediary, and/or sophisticated user doctrines.

Nineteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the lack of defect since Defendant's product was properly prepared in accordance with the applicable standard of care.

Twentieth Affirmative Defense

Plaintiff's claims are barred because, based on the state of scientific, medical, and technical knowledge at all relevant times, Abilify® was reasonably safe for its normal and foreseeable use, it was not unreasonably dangerous or defective, and its benefits exceeded any associated risks.

Twenty-First Affirmative Defense

Plaintiff's claims are barred because the methods, standards, and techniques used by OAPI in manufacturing, distributing, marketing, or labeling Abilify® and in issuing warnings

and instructions with respect to their use, conformed with the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, distributed, and used.

Twenty-Second Affirmative Defense

Plaintiff's claims grounded in state tort law and alleging Abilify® is unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article VI, clause 2.

Twenty-Third Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because OAPI's advertisements and labeling with respect to Abilify® were not false or misleading and, therefore, constitute protected speech under the applicable provisions of the United States Constitution.

Twenty-Fourth Affirmative Defense

To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate OAPI's rights under the United States Constitution.

Twenty-Fifth Affirmative Defense

Plaintiff is not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

Twenty-Sixth Affirmative Defense

Should OAPI be held liable to Plaintiff, which liability is specifically denied, OAPI asserts its entitlement to any and all applicable offsets, including but not limited to collateral source payments received by or available to Plaintiff.

Twenty-Seventh Affirmative Defense

Notwithstanding the claims and contentions of Plaintiff, Plaintiff received all or substantially all of the benefit from Abilify® that Plaintiff hoped and intended to receive, and to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from OAPI must be correspondingly reduced.

Twenty-Eighth Affirmative Defense

Plaintiff's breach of warranty claims are barred because OAPI did not breach any express or implied warranties and alternatively because Plaintiff did not rely on any such representation or warranty.

Twenty-Ninth Affirmative Defense

To the extent applicable, Plaintiff's breach of warranty claims are barred by a lack of privity between Plaintiff and OAPI and because Plaintiff failed to provide OAPI with reasonable or adequate notice of the alleged breach of any such purported warranties.

Thirtieth Affirmative Defense

Because of the lack of clear standards, the imposition of punitive damages against OAPI is unconstitutionally vague and/or overbroad.

Thirty-First Affirmative Defense

Plaintiff's claims for punitive damages are in violation of OAPI's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause in the Fifth Amendment of the United States Constitution; the Free Speech Clause of the First Amendment of the United States Constitution; the Commerce Clause of Article I, Section 8 of the United States Constitution; the Contracts Clause of Article I, Section

10 of the United States Constitution; similar provisions in the Constitution of Missouri and/or the common law and public policies of Missouri; and/or applicable statutes and court rules, in the circumstances of this litigation.

Thirty-Second Affirmative Defense

Defendant's acts or omissions were not malicious, willful, wanton, intentional, grossly negligent, or reckless, and therefore, any award of punitive damages is barred.

Thirty-Third Affirmative Defense

Plaintiff's claims based on statutes are barred, in whole or in part, by a failure to meet statutory prerequisites.

Thirty-Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the United States Food and Drug Administration (FDA) pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (FDCA) and regulations promulgated thereunder.

Thirty-Fifth Affirmative Defense

Plaintiff's claims are barred because the use of the product at issue was generally recognized as safe and effective pursuant to conditions established by FDA and applicable regulations, including packaging and labeling regulations. The conduct of OAPI, as well as the product Abilify®, conformed with the FDCA and the requirements of the FDA. Additionally, OAPI's activities and products alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

Thirty-Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, under the doctrine of primary jurisdiction since Defendant's applicable conduct with respect to Abilify® is managed under the supervision of the FDA.

Thirty-Seventh Affirmative Defense

Plaintiff's claims are barred by a failure to comply with all conditions precedent to any right to recover.

Thirty-Eighth Affirmative Defense

Plaintiff's Complaint is defective in that Plaintiff has failed to join necessary or indispensable parties to the action.

Thirty-Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff's use of Abilify® was based upon advice and information from third parties.

Fortieth Affirmative Defense

Defendant is entitled to and claims the benefit of all defenses and presumptions set forth in or arising from any rule of law or statute in this State and/or any other law or statute that may be applicable.

Forty-First Affirmative Defense

Defendant's conduct was not negligent and did not violate any duty owed to Plaintiff.

Forty-Second Affirmative Defense

Any recovery by Plaintiff is barred by the state of the art doctrine.

Forty-Third Affirmative Defense

To the extent that Plaintiff seeks to hold Defendant liable for a failure to warn, Defendant had no duty to warn the Plaintiff of the type of injuries alleged in the Complaint.

Forty-Fourth Affirmative Defense

Plaintiff did not detrimentally rely on any labeling, warnings, or other information concerning Abilify®.

Forty-Fifth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because OAPI made no false, material, or knowing misrepresentation to Plaintiff, nor did OAPI conceal or omit any material information from Plaintiff.

Forty-Sixth Affirmative Defense

The public interest, benefit, and availability of the product at issue outweigh the risks, if any, resulting from such activities, which were unavoidable given the state of knowledge at the time those activities were undertaken.

Forty-Seventh Affirmative Defense

At the time the product left OAPI's control, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product.

Forty-Eighth Affirmative Defense

Punitive damages are not available to Plaintiff because the drug at issue was subject to premarket approval or licensure by FDA under the Federal Food, Drug, and Cosmetic Act and was approved or licensed.

Forty-Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and/or standing to bring such claims.

Fiftieth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, under the laws of the state of residence of Plaintiff.

Fifty-First Affirmative Defense

Plaintiff has failed to properly plead the alleged claims with sufficient particularity.

Fifty-Second Affirmative Defense

OAPI did not make to Plaintiff or breach any express or implied warranties and did not breach any warranties created by law. Therefore, Plaintiff's claims for breach of warranties are barred, fail to state a claim, and should be dismissed with prejudice.

Fifty-Third Affirmative Defense

Under the applicable law, Plaintiff's claims for punitive and non-economic damages are capped and otherwise limited.

Fifty-Fourth Affirmative Defense

OAPI reserves the right to assert any and all other affirmative defenses, including but not limited to, those set forth in Rules 12(b) and 8(c) of the Federal Rules of Civil Procedure, which discovery may reveal are applicable.

OAPI requests that Plaintiff be denied the relief sought in the Complaint and that OAPI be dismissed from this action and awarded costs together with any additional relief that the Court deems just and proper. OAPI reserves the right to supplement its Answer and affirmative

defenses with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend its Answer accordingly.

WHEREFORE, OAPI prays for relief and judgment against Plaintiff as follows:

- A. That Plaintiff takes nothing by reason of the Complaint;
- B. That this action be dismissed with prejudice;
- C. That OAPI recovers its fees, costs, and attorneys' fees incurred herein; and
- D. Such further and other relief as the Court deems just and proper.

Dated: March 17, 2016

Respectfully submitted,

/s/ John L. Hayob

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*Attorneys for Defendant
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(Appearing Specially)*

CERTIFICATE OF SERVICE

I, John L. Hayob, hereby certify that on March 17, 2016, I caused a copy of the foregoing to be filed through the Court's CM/ECF system, which will serve all counsel of record.

/s/ John L Hayob

John L. Hayob